

21 JUL 2004

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
7 August 2003 (07.08.2003)

PCT

(10) International Publication Number
WO 03/063698 A1

(51) International Patent Classification⁷: A61B 5/00,
5/20, 5/22

(21) International Application Number: PCT/JP02/08389

(22) International Filing Date: 20 August 2002 (20.08.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2002-20178 29 January 2002 (29.01.2002) JP

(71) Applicant (for all designated States except US): NIHON
UNIVERSITY [JP/JP]; 8-24, Kudan-minami 4-chome,
Chiyoda-ku, Tokyo 102-8275 (JP).

(72) Inventor; and

(75) Inventor/Applicant (for US only): OMATA, Sadao
[JP/JP]; c/o NIHON UNIVERSITY, 8-24, Kudan-minami
4-chome, Chiyoda-ku, Tokyo 102-8275 (JP).

(74) Agents: ISHIHARA, Masanori et al.; ISHIHARA &
ISHIHARA, 4F, Miyamasuzaka ST Building, 8-6, Shibuya
1-chome, Shibuya-ku, Tokyo 150-0002 (JP).

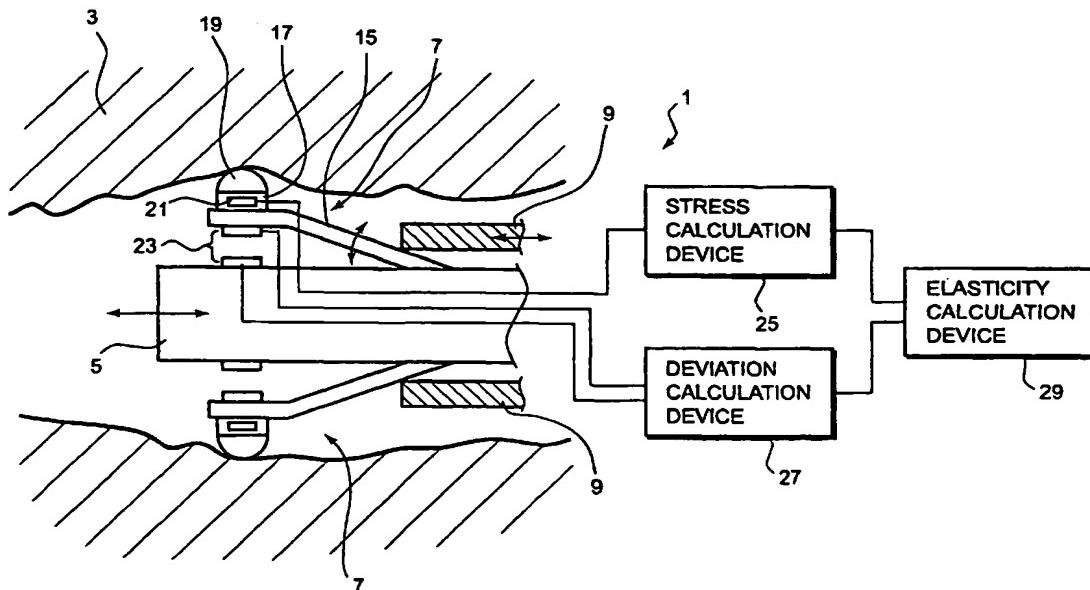
(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,
SI, SK, SL, TI, TM, TN, TR, TT, TZ, UA, UG, US, UZ,
VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK,
TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report

[Continued on next page]

(54) Title: ELASTICITY MEASURING DEVICE FOR BIOLOGICAL TISSUE



WO 03/063698 A1

(57) Abstract: We disclose an elasticity-measuring device which can be inserted into a canal part of living body and which is capable of quantitatively measuring the elasticity of the biological tissue of inner side of canal part. The device consists of a probe base (5) and probes (7). The probes (7) are secured to probe base (5) and driven to press onto and return from biological tissue. According to the stress or hardness of the biological tissue measured by sensors on probes (7) and to the deviation between the probes (7) and the probe base (5), we can decide the elasticity of the biological tissue of inner side of canal part quantitatively.



— *with amended claims and statement*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ELASTICITY MEASURING DEVICE FOR BIOLOGICAL TISSUE

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 The present invention relates to a device for measuring the elasticity of the biological tissue.

2. Description of the Related Art

In the case of women, after the delivery of a child or in accordance with the aging, since the muscle suspending the urethra goes slacked and hence its elasticity deteriorates, there is a tendency that incontinence occurs even for slight shock or impact. To cope with this physical problem, an operation for restoring the elasticity of the muscle suspending the urethra is performed in such way that suspension holes are provided in, for example, pelvis and the muscles around the urethra are suspended with the usage of the suspension holes. To perform an appropriate operation, it is necessary to evaluate an elasticity of the muscles that surround the urethra.

20 Since the urethra is located near the vagina, the evaluation of elasticity of the muscles surrounding the urethra can be conducted by measuring the elasticity of the biological tissue of an inner surface of a canal part of the vagina. However, since one of the functions of the 25 muscles surrounding the urethra is to enlarge and contract

the urethra with an appropriate elasticity, even if the conventional elasticity coefficient or factor for the biological tissue which is represented by the simple ratio of stress and distortion is used, it is impossible to sufficiently evaluate its elasticity characteristics such as viscoelasticity. Since the diameter of the vagina is in the order of 15 mm, it is possible to insert a probe in the canal part thereof. However, in the prior art, there has been no appropriate probe and measuring method for measuring the above elasticity of the muscles that surround the canal part of the vagina and suspend the urethra. Accordingly, the determination of the degree of elasticity deterioration of the muscle around the urethra and the degree of suspending the muscles upwardly using the suspension holes for restoring the elasticity is still made through a diagnosis relied on experiences such as the palpation of the operator's fingers.

SUMMARY OF THE INVENTION

It is, therefore, an object of the present invention to overcome the above problems in the prior art.

It is another object of the present invention to provide an elasticity measuring device for biological tissue which is capable of quantitatively measuring the elasticity of an inner portion of canal part of the biological

body.

According to one aspect of the invention, there is provided an elasticity measuring device for being inserted into a canal part of a human body and for measuring elasticity of the inner side of the canal part of the human body, the device comprising:

a probe base for being inserted into the canal part of the human body;

a plurality of probes symmetrically arranged around the probe base, which are located near the inner side of the canal part of the biological tissue when the device is inserted into the canal part and are driven to press onto and return from the biological tissue;

a stress detection sensor provided on each of said probes, for detecting the stress applied to the biological tissue based on the repulsion from the biological tissue when said probes are driven to press onto and return from the biological tissue; and

a deviation detection sensor for detecting the change of said stress detection sensor with respect to the probe base,

wherein the elasticity of the biological tissue is measured based on the stress and deviation magnitude characteristics when the probes are driven to press onto and return from the biological tissue.

According to another aspect of the invention, there is also provided an elasticity measuring device for being inserted into a canal part of a human body and for measuring elasticity of the inner side of the canal part of the 5 biological tissue, the device comprising:

a probe base for being inserted into the canal part of the human body;

a plurality of probes symmetrically arranged around the probe base, which are located near the inner side of 10 the canal part of the biological tissue when the device is inserted into the canal part and are driven to press onto and return from the biological tissue;

a hardness sensor provided on each of the probes, for outputting a signal indicative of hardness of the biological 15 tissue;

a hardness detection means for detecting the hardness of the biological tissue based on the signal from the hardness sensor; and

a deviation detection sensor for detecting the deviation magnitude of the hardness sensor with respect to the probe base,

wherein the elasticity of the biological tissue is measured based on the hardness characteristics when the probes are driven to press onto and return from the biological 25 tissue.

In the above elasticity measuring device of the invention, it is preferable that each of the probes comprises a balloon which is hydraulically expandable and contractable and is driven to press onto and return from
5 the biological tissue.

In the above elasticity measuring device of the invention, the hardness sensor comprises a vibration element and a vibration detection sensor. The hardness detection means comprises an input terminal connected to the vibration detection sensor; an output terminal connected to the vibration element; an amplifier having an input coupled to the input terminal; and a phase shift circuit connected between an output terminal of the amplifier and the output terminal, for changing a frequency and making a phase difference zero (0) when there occurs a phase difference between input waveforms applied to the vibration element and output waveforms forwarded from the vibration detection sensor. With the device having the above structure, while a resonant state of the closed loop circuit including the
10 hardness sensor and the biological tissue is maintained,
15 hardness of the biological tissue is preferably detected by the frequency change caused by the change in hardness of the biological tissue.
20

The elasticity measuring device for the biological
25 tissue of the present invention comprises a probe base for

being inserted into the canal part of the human body, and
a plurality of probes symmetrically arranged around the

probe base, which are located near the inner side of the
canal part of the biological tissue when the device is

5 inserted into the canal part and are driven to press onto
and return from the biological tissue. The contact pres-
sure against the biological tissue, that is, the stress
when the probes are driven to press onto and return from
the biological tissue is detected by the stress detection
10 sensor as hysteresis. Also, the deviation magnitude of the
stress detection sensor with respect to the probe base,

that is, the deviation magnitude of expansion and contrac-
tion of the biological tissue is detected by the deviation
detection sensor as hysteresis. Based on these hysteresis

15 data, the hysteresis of the stress and deviation magnitude
characteristics of the biological tissue is evaluated and,
hence, the elasticity of the biological tissue, for exam-
ple, the viscoelasticity is measured and evaluated experi-
mentally and quantitatively.

20 The elasticity measuring device for the biological
tissue of the present invention comprises a probe base for
being inserted into the canal part of the human body, and
a plurality of probes symmetrically arranged around the
probe base, which are located near the inner side of the
25 canal part of the biological tissue when the device is

inserted into the canal part and are driven to press onto and return from the biological tissue. The hardness of the biological tissue when the probes are driven to press onto and return from the biological tissue is detected as hysteresis by the hardness detection means based on the signal of the hardness sensor provided on the probe. Also, the deviation magnitude of the hardness sensor with respect to the probe base, that is, the deviation magnitude of expansion and contraction of the biological tissue is detected by the deviation detection sensor as hysteresis.

Based on these hysteresis data, the hysteresis of the hardness and deviation magnitude characteristics of the biological tissue can be evaluated. Since the hardness has an intimate or close relationship to the elasticity coefficient which is a ratio between the stress and distortion, the elasticity of the biological tissue can be quantitatively measured based on analysis of the hysteresis.

The driving of the probes to press onto and return from the biological tissue may well be achieved by the balloon that is hydraulically expanded and contracted, other than the plate spring and motor mechanism.

In one embodiment of the elasticity measuring device of the invention, the device comprises a phase shift circuit which functions to change the frequency and make the phase difference zero (0) when there occurs a phase dif-

ference between the input waveforms applied to the vibration element and the output waveforms detected by the vibration detection sensor. With the device having the above construction, while the resonance state of the closed loop circuit including the hardness sensor and the biological tissue is maintained, the hardness of the biological tissue can be quantitatively detected based on the frequency change caused by the change in hardness of the biological tissue, whereby reliability of quantitative evaluation of hardness hysteresis is highly enhanced.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other objects, features and advantages of the present invention will be apparent from the following description of preferred embodiments of the invention explained with reference to the accompanying drawings, in which:

Fig. 1 is a view showing an embodiment of the elasticity measuring device of the invention in the state wherein the device is inserted in the canal part of the human body;

Fig. 2 is a view for explaining the movement of the probe when the probe base and the sleeve arranged around are moved relatively with each other in the longitudinal axial direction;

Fig. 3 is a view showing another embodiment of the elasticity measuring device of the invention in which balloons are secured to the probe base as the probes;

Fig. 4 is a view showing the details of the foremost 5 end of the probe of the elasticity measuring device of the invention;

Fig. 5 is a graph showing the changes in the stress F (vertical line) and the deviation magnitude X (horizontal line) when the probes of the device of the invention are 10 driven to press onto and return from the desired measuring portion;

Fig. 6 is graphs showing exemplary measured elasticity characteristics when the measurements are conducted at different three points of the canal part of the human 15 body; and

Fig. 7 is a view showing a still further embodiment of the elasticity measuring device of the invention using a hardness detection device.

20

PREFERRED EMBODIMENTS OF THE INVENTION

Now, some preferred embodiments of the present invention are explained hereunder with reference to the accompanying drawings. Fig. 1 shows a state in which the elasticity measuring device 1 of the invention is inserted in 25 the canal part of the human body 3. The elasticity measur-

ing device 1 comprises a probe base 5 in the form of an elongated bar having a few mm square or a few mm diameter in section, and a probe 7 secured to the probe base 5, a tip portion of which contacts the inner portion of the 5 canal part 3 of the biological tissue and which is driven to press onto and return from the biological tissue to be measured. To the outer surface of the probe base 5, there is provided a sleeve 9 which has a slightly larger inner diameter than the dimension of the outward form of the 10 probe base 5 and which is movable on the probe base 5 in the elongated axial direction of the probe base 5.

The probe 7 includes a plurality of plate springs 15 which are symmetrically arranged at the outer periphery of the probe base 5, a plurality of stress detection bases 17 15 correspondingly arranged at the foremost ends of the plate springs 15, and a plurality of contact balls 19 made of plastics in the form of substantial hemisphere. The probe 7 further includes a stress detection sensor 21 adhered to each stress detection base 17. A pair of deviation detection sensors 23 are arranged in such a way that one element 20 is secured to the one side of the plate spring 15 whose side is opposite to the side where the stress detection base 17 is secured and the other element is secured to a surface of the probe base 5 which surface is opposing 25 to the side where the one element is secured. The stress

detection sensor 21 and the deviation detection sensors 23 are connected to a stress calculation device 25 and a deviation calculation device 27, respectively, through corresponding signal lines. The outputs of both the stress 5 calculation device 25 and the deviation calculation device 27 are input to an elasticity calculation device 29. The probes 7 are four (4) in number and are arranged around the probe base 5 in a symmetrical relation. The symmetrical relation of the probes 7 is important for the probe 10 base to keep a stationary state when the measuring device is inserted in the canal part of the human body.

Fig. 2 is an illustration for explaining the movement of the probe 7 when the probe base 5 and the sleeve 9 arranged around the probe base 5 are moved relatively with 15 each other in the longitudinal axial direction. When the sleeve 9 is moved, for example, leftward in Fig. 2 with respect to the probe base 5, the tubular inner side of the sleeve 9 urges the plate spring 15 of the probe 7, and, in the further advancement of the sleeve 9 in the leftward, 20 it functions to press the plate spring 15 against the probe base side 5. Accordingly, a contact ball 19 arranged at the foremost end of the probe 7 moves downward in the drawings as the sleeve 9 moves in the leftward, whereas it moves upward as the sleeve 9 moves in the rightward. In 25 this way, the contact ball 19 at the foremost end of the

probe 7 can be driven to press onto and return from the biological tissue by the simple relative movement between the sleeve 9 and the probe base 5. The relative movement between the sleeve 9 and the probe base 5 can be achieved 5 by such small motor as a micro-motor (not shown in the drawings). Further, in the case of a simple measurement, such relative movement between the sleeve 9 and the probe base 5 can be performed manually by the operator's hands and fingers.

10 With the leftward movement of the sleeve 9, the probe 7 including the contact ball 19 can be entirely accommodated within the sleeve 9. In this case, since the elasticity measuring device 1 for the biological tissue can be inserted to a desired portion of the biological tissue to 15 be measured in the state in which the probe 7 having the complicated structure is fully accommodated within the sleeve 9 being kept, the insertion of the device can be effected smoothly. Thereafter, at the desired measuring position after the insertion, the four probes 7 can be 20 opened and closed in an umbrella fashion by the movement of the sleeve 9. The number of the probes is not limited to four as in the above embodiment, and it may well be any appropriate number, for example, one, two, three, six and so on.

25 As the structure of the probe which is driven to

press onto and return from the biological tissue, other than the above explained plate spring structure, a balloon which is hydraulically expandable and contractable may well be adopted. Fig. 3 shows such embodiment in which a 5 plurality of balloons 11 are secured to the probe base 5. The balloon 11 is hydraulically communicated with a pump 13 and is driven to press onto and return from the biological tissue by the control of the output pressure of the pump 13.

10 Fig. 4 shows in detail the foremost portion of the probe 7 shown in Fig. 1. To the foremost end of the plate spring 15, there is adhered the hemispherical contact ball 19 made of plastics having the stress detection base 17 on the surface thereof opposing to the biological tissue. The 15 stress detection sensor 21 is arranged within the stress detection base 17. The stress detection sensor 21 is a distortion guage and is firmly adhered to the stress detection base 17 using an adhesive agent. To the side of the plate spring 15 whose side is an opposite side where 20 the reaction detection base 17 is arranged, there is provided a light receiving element. A light emitting element opposing to the light receiving element is provided on the surface of the probe base 5. The above pair of light emitting and light receiving elements constitutes the deviation 25 detection sensor 23. The stress detection sensor 21

and the deviation detection sensor 23 are connected to the stress calculation device 25 and the deviation calculation device 27, respectively, by the respective signal lines. Though the stress detection base 17 and the contact ball 5 19 are made of the same material, they may well be made of different materials and may well be in a stacked configuration. The deviation detection sensor, which is constituted by a pair of the light emitting and light receiving element in the illustrated embodiment, may well be constituted by a combination of a magnet and a magnetic sensor, 10 15 for example, or other small contactless sensor.

Next, actual operation of the device having the above structure will be explained hereunder. The probe base 5 with the four probes 7 arranged symmetrically around the probe base 5 being closed in an umbrella fashion is inserted into the canal part of the human body, namely, the vagina of the patient. Then, at the position where the elasticity of the biological tissue is to be measured, the probes 7 are opened by gradually moving the sleeve 9 relative to the probe base 5 in the rightward in Fig. 1. By so doing, the contact ball 19 moves toward the biological tissue side and urges to press against the biological tissue of the canal part. Thereafter, the sleeve 9 is gradually moved or returned in the leftward with respect to the 20 25 probe base 5 so that the probes 7 are folded. The stress F

from the biological tissue at every moment when the probes drive to press onto and return from the biological tissue is detected by a pressure detection sensor 21 which is arranged on the stress detection base 17 to which the contact ball 19 is also provided. In the case where the pressure detection sensor is a distortion guage, the detected result as the variations in resistance is forwarded to the stress calculation device 25 by a signal line and converted to the corresponding stress after the necessary 10 calculation process.

The change in distance of the contact ball 19 with respect to the probe base 5, that is, the relative variation occurring when the contact ball 19 is driven to press onto and return from the biological tissue 3 is detected 15 by the deviation detection sensor 23. Specifically, as the distance of the contact ball 19 with respect to the probe base 5 changes, the distance between the paired light emitting and receiving elements 23 changes accordingly. The change in the amount of received light corresponding 20 to the change in the above distance is forwarded to the deviation amount calculation device 27 through the signal line and the magnitude of deviation is obtained thereat after the necessary calculation process.

In this way, the stress F and the corresponding deviation magnitude X are obtained under the condition where 25

the probes are driven to press onto and return from the biological tissue. The probe base 5 is positioned stationary at the desired measuring point of the biological tissue after the insertion and, then, in the case of Fig. 1 5 illustration, the sleeve 9 is gradually moved in the rightward with respect to the probe base 5 and then gradually moved to the leftward again. By so doing, the contact ball 19 is first pressed against the biological tissue and then returned therefrom. Specifically, by making the 10 stress F and the changes in the deviation magnitude X have correlation, it is possible to analyze the hysteresis of the elasticity of the biological tissue. Fig. 5 is an exemplary graph which shows the changes in the stress F and the deviation magnitude X of the biological tissue when 15 the probe 7 is driven to press onto and return from the biological tissue at the desired measuring point. The vertical line denotes the stress F and the horizontal line denotes the deviation magnitude X. As shown in Fig. 5, as a hysteresis curve of the elasticity of the biological 20 tissue can be obtained, it has been made possible to measure and evaluate the elasticity of the biological tissue experimentally and quantitatively. The viscoelasticity of the biological tissue can be quantitatively evaluated by, for example, the size of area surrounded by the obtained 25 hysteresis curve.

Fig. 6 shows exemplary graphs of the elasticity when the measurements are conducted at different three points of the canal part of the human body. At the three points A, B and C where the depth of the insertion of the probe 5 base 5 into the canal part of the human body are different from one another, the probes 7 are driven to press onto and return from the inner side of the canal part of the human body, the hysteresis characteristics of the stress F and the deviation magnitude X at that time are obtained 10 and illustrated for the purpose of comparison with the stress F taken as the vertical line and the deviation magnitude X taken as the horizontal line. For example, comparing the hysteresis characteristics at the point A with those at the point B or C, since the area surrounded by 15 the hysteresis curve at the point A is smaller than the area at the point B or C, it can be quantitatively evaluated that the elasticity at the point A is greater than the elasticity at the point B or C.

As has been explained hereinabove, it has been made 20 possible to measure and evaluate the elasticity of the biological tissue by evaluating or analyzing the hysteresis characteristics between the stress and the distortion based on the measurements of the stress and the distortion of the biological tissue. On the other hand, since the 25 hardness has an intimate or close relationship to the

elasticity coefficient which is a ratio between the stress and the distortion, it is also possible to quantitatively measure and evaluate the elasticity of the biological tissue based on the hysteresis of the hardness.

5 Fig. 7 is a block diagram showing another embodiment of the elasticity measuring device for the biological tissue according to the invention, in which the hardness of the biological tissue is measured. A hardness sensing device 41 includes a vibration element 43 and a vibration detector 45 at the foremost end portion of the probe 7.

10 The vibration element 43 and the vibration detector 45 are connected to an output terminal 47 and an input terminal 49, respectively, of a hardness detection means 51. The hardness detection means 51 includes an amplifier 53 whose

15 input node is coupled to the input terminal 49, and a phase shift circuit 55 connected between an output node of the amplifier 53 and the output terminal 47. The phase shift circuit 55 operates to change the frequency and make the phase difference zero (0) when there occurs a phase

20 difference between the input waveforms applied to the vibration element 43 and the output waveforms forwarded from the vibration detector 45. The detail of such phase shift circuit having the above functions is disclosed in the Japanese Patent Application Kokai-Publication No. Hei 9-

25 145691 which should be incorporated by reference in this

application.

In the device having the above construction, while the resonance state of the closed loop circuit including the hardness sensor 41 and the biological tissue is maintained, the change in frequency caused by the change in hardness of the biological tissue is detected by the frequency deviation detection circuit 57 and, then, the detected change is converted to the value of hardness by the hardness converter 59. In this way, with the probe being driven to press onto and return from the biological tissue, hysteresis characteristics in relation to the hardness of the biological tissue can be quantitatively measured and obtained.

With the elasticity measuring device for the biological tissue according to the present invention, the elasticity of the measured biological tissue can be quantitatively measured by simply inserting the canal part of the human body with additional simple operation being followed.

While the invention has been described in its preferred embodiments, it is to be understood that the words which have been used are words of description rather than limitation and that changes within the purview of the appended claims may be made without departing from the true scope of the invention as defined by the claims.

C L A I M S

1. An elasticity measuring device for being inserted into a canal part of a human body and for measuring elasticity of the inner side of the canal part of the human
5 body, said device comprising:

a probe base for being inserted into the canal part of the human body;

at least one probe arranged around said probe base, which is located near the inner side of the canal part of
10 the human body when the device is inserted into the canal part and is driven to press onto and return from the biological tissue;

a stress detection sensor provided on said probe, for detecting the stress applied to the biological tissue
15 based on the repulsion from the biological tissue when said probe is driven to press onto and return from the biological tissue; and

a deviation detection sensor for detecting the change of said stress detection sensor with respect to said probe
20 base,

wherein the elasticity of the biological tissue is measured based on the stress and deviation magnitude characteristics when the probe is driven to press onto and return from the biological tissue.

2. An elasticity measuring device for biological tissue according to claim 1, in which a plurality of said probes are symmetrically arranged around said probe base through corresponding spring members.

5

3. An elasticity measuring device for biological tissue according to claim 2, in which said deviation detection sensor comprises a pair of light emitting element and light receiving element, said light emitting element being secured on a surface of said probe base and said light receiving element being secured on said spring member so as to oppose to each other.

10
15 4. An elasticity measuring device for biological tissue according to claim 1, in which said stress detection sensor comprises a distortion guage.

20 5. An elasticity measuring device for being inserted into a canal part of a human body and for measuring elasticity of the inner side of the canal part of the human body, said device comprising:

a probe base for being inserted into the canal part of the human body;

25 at least one probe arranged around said probe base, which is located near the inner side of the canal part of

the biological tissue when the device is inserted into the canal part and is driven to press onto and return from the biological tissue;

5 a hardness sensor provided on said probe, for outputting a signal indicative of hardness of the biological tissue;

a hardness detection means for detecting the hardness of the biological tissue based on the signal from said hardness sensor; and

10 a deviation detection sensor for detecting the deviation magnitude of said hardness sensor with respect to said probe base,

wherein the elasticity of the biological tissue is measured based on the hardness characteristics when the 15 probe is driven to press onto and return from the biological tissue.

6. An elasticity measuring device for biological tissue according to claim 5, wherein said hardness sensor comprises:

a vibration element; and

a vibration detector, and wherein said hardness detection means comprises:

an input terminal connected to said vibration detec-

25 tor;

an output terminal connected to said vibration element;

an amplifier having an input coupled to said input terminal; and

5 a phase shift circuit connected between an output terminal of said amplifier and said output terminal, for changing a frequency and making a phase difference zero (0) when there occurs a phase difference between input waveforms applied to said vibration element and output

10 waveforms forwarded from said vibration detector,

wherein, while a resonant state of the closed loop circuit including said hardness sensor and the biological tissue is maintained, hardness of the biological tissue is detected by said frequency change caused by the change in

15 hardness of the biological tissue.

7. An elasticity measuring device for biological tissue according to claim 1 or 5, in which said probe comprises a balloon which is hydraulically expandable and contractable

20 and is driven to press onto and return from the biological tissue.

AMENDED CLAIMS

[received by the International Bureau on 27 November 2002 (27.11.02);
original claims 5 amended; remaining claim unchanged (1 pages)]

the biological tissue when the device is inserted into the canal part and is driven to press onto and return from the biological tissue;

5 a hardness sensor provided on said probe, for outputting a signal indicative of hardness of the biological tissue;

 a hardness detection means for detecting the hardness of the biological tissue based on the signal from said hardness sensor; and

10 a deviation detection sensor for detecting the deviation magnitude of said hardness sensor with respect to said probe base,

 wherein the elasticity of the biological tissue is measured based on the hardness and deviation characteristics when the probe is driven to press onto and return from the biological tissue.

6. An elasticity measuring device for biological tissue according to claim 5, wherein said hardness sensor comprises:

 a vibration element; and

 a vibration detector, and wherein said hardness detection means comprises:

 an input terminal connected to said vibration detector;

STATEMENT UNDER ARTICLE 19(1)

In claim 5, on line 14, after "hardness", we amend to insert --and deviation--.

The deviation detection sensor of the instant invention is not disclosed or suggested in the cited documents. For making this point clear, claim 5 is amended as above.

Other claims are retained unchanged.

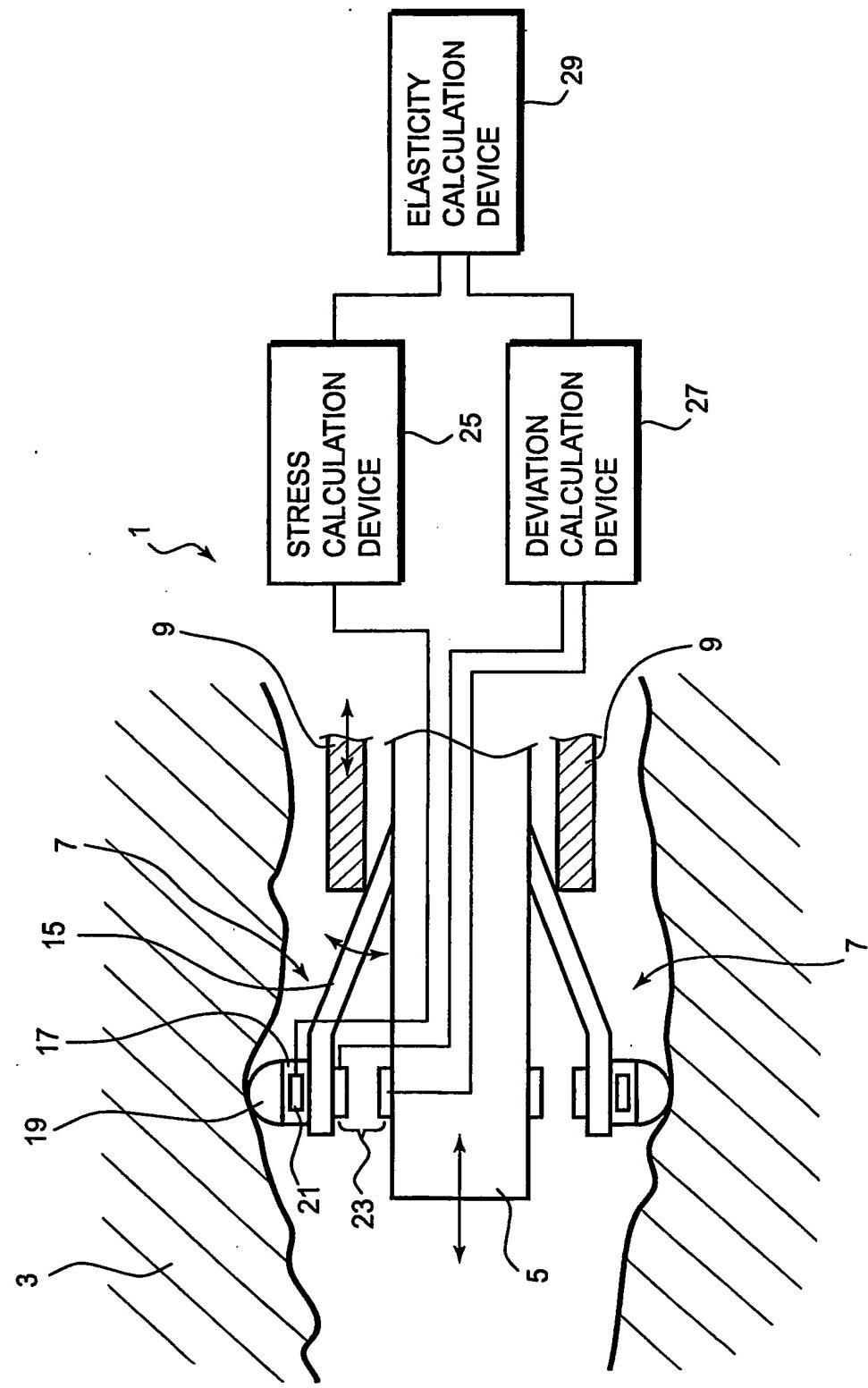
Fig. 1

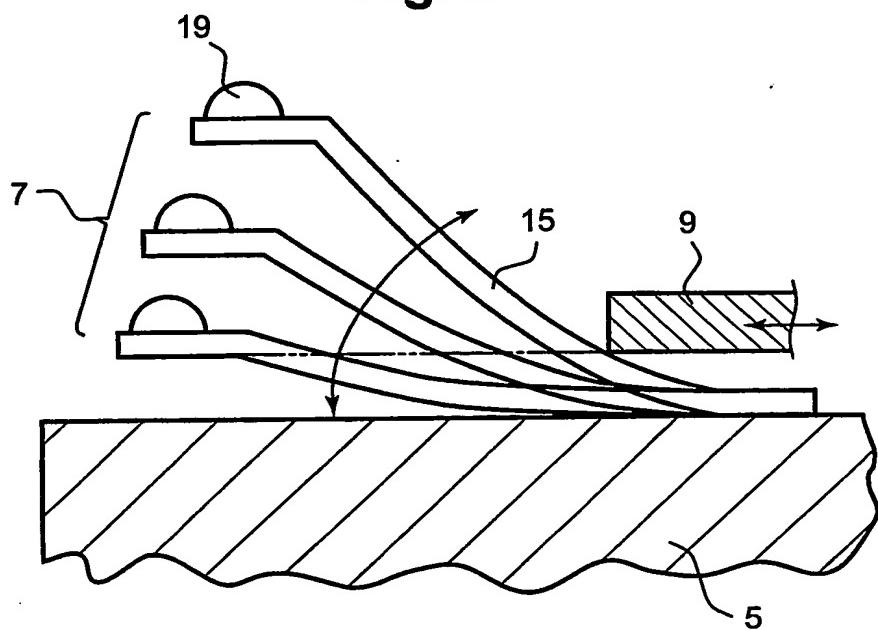
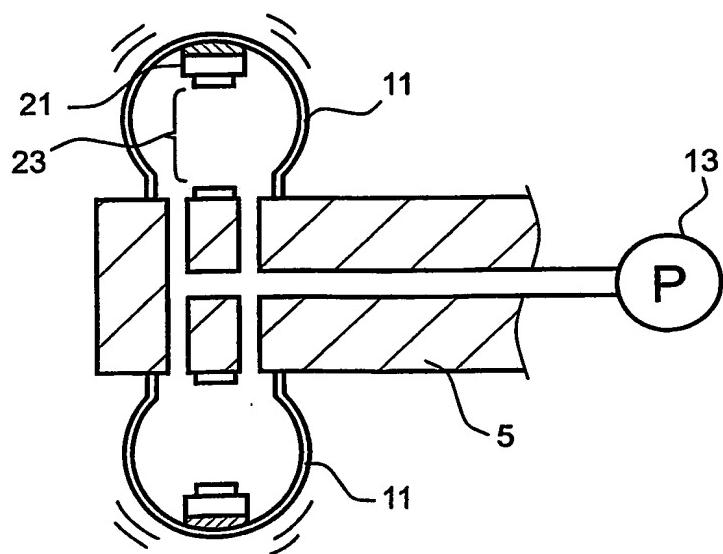
Fig. 2**Fig. 3**

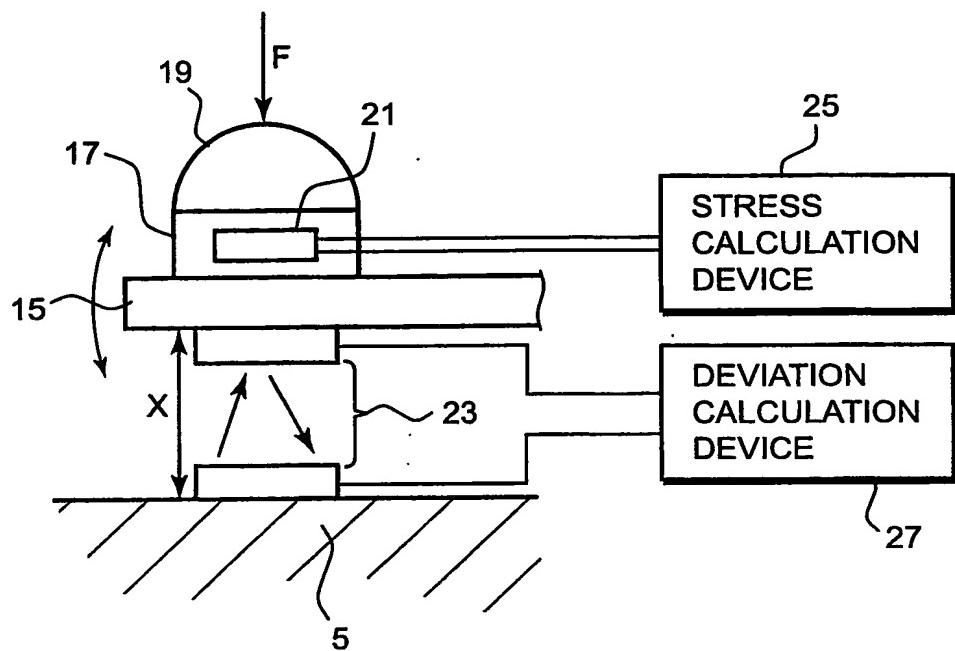
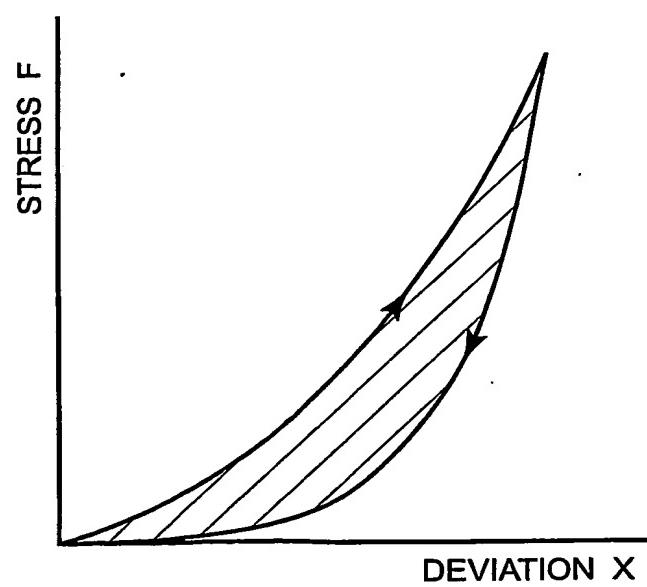
Fig. 4**Fig. 5**

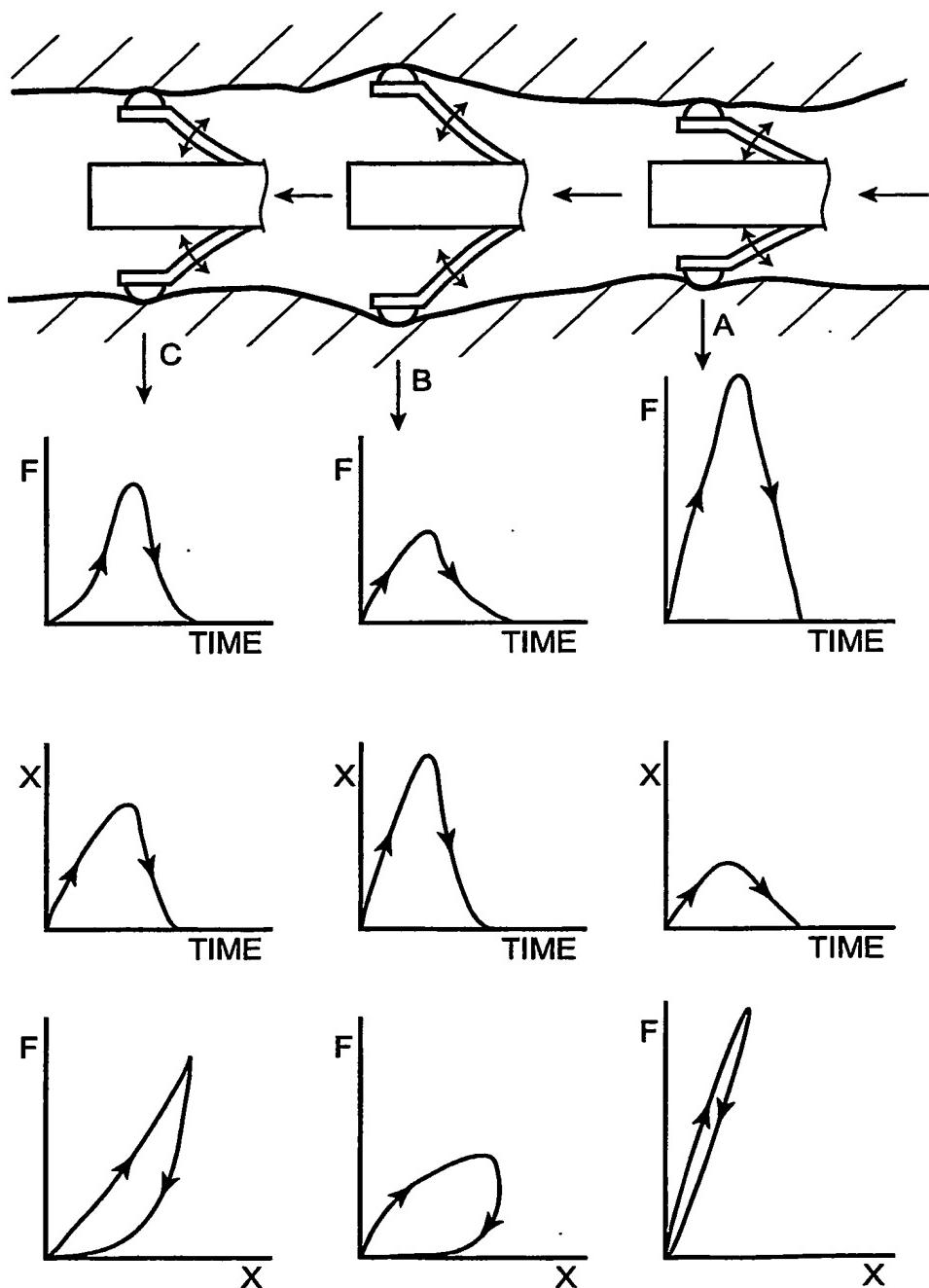
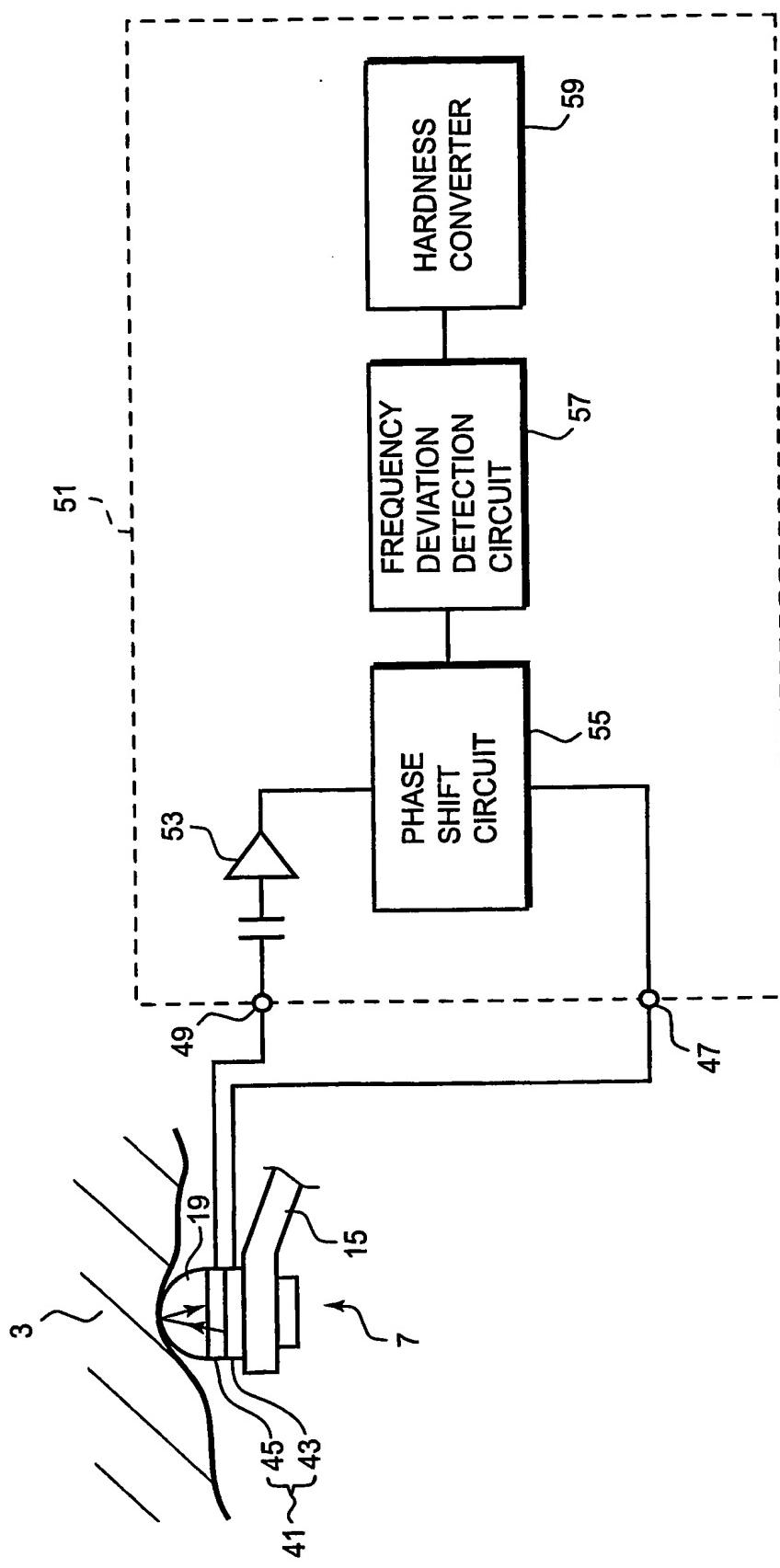
Fig. 6

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP02/08389

A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl' A61B 5/00 , A61B5/20 , A61B5/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl' A61B 5/00 , A61B5/20 , A61B5/22 , A61B10/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
 Japanese Utility Model Gazette 1926-1996, Japanese Publication of Unexamined Utility Model Applications 1971-2002, Japanese Registered Utility Model Gazette 1994-2002, Japanese Gazette Containing the Utility Model 1996-2002

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

JOIS (JICST Files)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 4-19862 B2 (Universite Rene Descartes) 1992.03.31, see all document, Fig.1-7	1,2,4
Y	& US 4566465 A & FR 2543834 A & GB 2137499 A	5,6
A	JP 3151153 B2 (Sadao Omata, & Axiom Co.,Ltd) 2001.01.19, see all document, Fig.1-38 & US 5766137 A & EP 764842 A2 & AU 709813 B	3,7
Y	JP 3-54575 B2 (Muneyuki MORIKAWA, etc.) 1991.08.20, see all document, Fig.1-6 (Family:none)	5,6
A		1-7

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	
"A"	document defining the general state of the art which is not considered to be of particular relevance
"E"	earlier application or patent but published on or after the international filing date
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O"	document referring to an oral disclosure, use, exhibition or other means
"P"	document published prior to the international filing date but later than the priority date claimed
"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&"	document member of the same patent family

Date of the actual completion of the international search

12.09.02

Date of mailing of the international search report

01.10.02

Name and mailing address of the ISA/JP

Japan Patent Office

3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan

Authorized officer

YOSHIHITO ITO

Telephone No. +81-3-3581-1101 Ext. 3291

Seal	2W	9604
------	----	------